

Lamb SE, Hansen Z, et al. Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. Lancet 2010;375:916-23.

Design: Group randomized clinical trial

Population/sample size/setting:

- 701 patients (420 women, 281 men, mean age 54) treated for low back pain at a clinical trials unit of Warwick Medical School in the UK
- Eligibility criteria were age over 18 with low back pain of at least 6 weeks duration, and at least one physician visit in the previous 6 months
- Exclusion criteria were severe psychological problems, previous participation in cognitive-behavioral treatment (CBT), concern from the primary physician about the possibility of a serious cause of back pain (infection, fracture, tumor)

Main outcome measures:

- Patients were randomized 2:1 to either CBT (n=468) or advice alone as a control group (n=233)
- All patients received a 15 minute session of active management advice (avoid bed rest, stay active, appropriate use of medication, symptom management) and a copy of *The Back Book*
- Control group received no additional intervention as part of the trial, but was free to seek further care
- CBT group attended a Back Skills Training program, which included 6 sessions of 1.5 hour duration of group therapy (average of 8 participants per group); this consisted of guided discovery, identifying and countering negative automatic thoughts, pacing, graded activity, relaxation, and other skills; each session was supplemented with a workbook
- Compliance was defined as attendance at the initial assessment and at least three subsequent CBT sessions; 63% of CBT group met the threshold
- Selected sessions were recorded to assess therapist competence with good cognitive-behavioral practice
- Main outcome measures were twofold: changes from baseline on the Roland-Morris Disability (scale from 0-24, with low scores meaning less disability), and changes from baseline on a modified Von Korff scale (0-100%, low scores meaning less pain and disability)
- Several secondary outcomes were measured, including mental and physical scales of SF-12, fear-avoidance beliefs questionnaire, and self-rated benefit from treatment
- Outcomes were measured at 3 months, 6 months, and 12 months
- Follow-up was 85% at 12 months; the most frequent reason for withdrawal was unwillingness to complete questionnaires
- CBT was superior to control on almost all outcomes at 3, 6, and 12 months
- At 12 months, the CBT and control group changes in Roland-Morris scores were 2.4 and 1.1 points; the changes in Von Korff scale for disability were

13.8% and 5.4%; the changes in Von Korff scale for pain were 13.4% and 6.4% respectively

- Fear-avoidance beliefs, pain self-efficacy, and SF-12 physical scores also showed an advantage for CBT over control
- Cost-effectiveness was measured Quality-adjusted life-year (QALY) gains were measured using the European Quality of Life (EQ-5D); the cost per QALY for CBT was £1786.

Authors' conclusions:

- The CBT program was effective in managing subacute and chronic back pain in primary care, at a cost less than half of all competing interventions (manipulation, acupuncture, exercise, and postural approaches)
- A potential limitation of the study is that patients were identified through record searches of primary care doctors rather than during consultations; however, since all participants had had at least 1 consultation in the previous 6 months, this is probably not a serious limitation

Comments:

- Blinding is clearly not applicable; other indicators of control of bias (randomization, allocation concealment) were adequately done
- The large number of participants and good follow-up, with multiple outcome measurements at different time points, is an additional advantage
- The change in Roland-Morris disability scale is small, but the change in Von Korff scale is probably clinically relevant
- The exclusion criteria listed did not include leg pain, but it is clear that patients with leg pain were not included in the study, and the results are not applicable to this group of low back pain patients

Assessment: High quality for good evidence that group CBT is beneficial and cost-effective in improving function and alleviating pain in patients with uncomplicated subacute and chronic low back pain